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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,228	03/14/2001	Brian W. McKinnon	10557/199332	5554

30559 7590 12/02/2003

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EXAMINER

BARRETT, THOMAS C

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,228

Applicant(s)

MCKINNON, BRIAN W.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-181 is/are pending in the application.
- 4a) Of the above claim(s) 1-101, 111-115, 131-134, 136, 137, 140-142 and 144-181 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 102-110, 116-130, 135, 138, 139 and 143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed September 8, 2003 have been fully considered but they are not persuasive.

Regarding claims 107-110, the indefinite nature of the claims is not that they recite, "a femoral component as a further required component". It is because they recite "a femoral component ***employed...***" which is a ***process*** of using the femoral component to define the surface. The preamble is directed to a device, not a process.

Regarding the arguments towards claims 102-110, 116-130, 135, 138-139 and 143, if in fact the Applicant is claiming a "product-by-process", the Applicant is required to supply evidence. Where the claimed and prior art products are identical or substantially identical in structure or composition, a *prima facie* case of either anticipation or obviousness has been established. The *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. The Applicant has failed to supply any evidence that the prior art products do not necessarily possess the characteristics of the claimed product.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 107-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 107-108 are ambiguous and therefore indefinite as to whether the Applicant is claiming a product ("femoral component" or a process ("**employing** femoral components to define said sculpted surface").

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

And

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 102-106, 135, 138-139 and 143 are rejected under 35 U.S.C. 102(b) as anticipated by Thornberry et al. as disclosed in applicant's IDS. Thornberry et al. disclose a prosthetic device comprising: an acetabular shell, an acetabular liner and a femoral component. (See "Results and Discussion"). The shape of the sculpted surface varies around the rim of the liner ("wide chamfer") and is symmetric about a plane ("small chamfer").

Claims 102 and 116 are rejected under 35 U.S.C. 102(a) as anticipated by Harkess et al. as disclosed in applicant's IDS. Harkess et al. discloses a prosthetic device comprising: an acetabular shell, an acetabular liner and a femoral component.

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The shape of the sculpted surface varies around the rim of the liner ("wide chamfer") and is symmetric about a plane (Design B).

Claims 102 and 117-124 are rejected under 35 U.S.C. 102(b) as anticipated by Smith & Nephew (Reflection Lateralized Liners...) as disclosed in applicants IDS. Smith & Nephew discloses a prosthetic device comprising: an acetabular shell and an acetabular liner. The liner has a distance across the opening of the internal concave surface of 28mm, a shoulder, a serrated locking surface and a lateral offset of 4mm. The external surface of the "Lateralized Liners" is adapted to be received in a "Reflection InterFit" acetabular shell, which, as disclosed in the "Catalog Information" of "Smith & Nephew Surgical Technique" as cited in applicant's IDS, has an external diameter of 42-76 mm.

Claims 102 and 126-130 are rejected under 35 U.S.C. 102(b) as anticipated by Lennox. Lennox discloses a prosthetic device comprising: an acetabular shell and an acetabular liner (Fig. 1). The liner has a center axis oriented 20 degrees to the axis of the shell (col. 8, lines 51-64).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 102, 122 and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bateman et al. Bateman et al. discloses a prosthetic device comprising: an acetabular shell, an acetabular liner and medially shifted liner (Fig. 4) however Bateman et al. fails to disclose the liner shifted medially specifically up to 8 mm.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to shift the liner medially specifically up to 8 mm. Applicant has not disclosed that shifting the liner medially specifically up to 8 mm provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the liner medially shifted specifically up to 8 mm because there is no disclosed advantage over a specific length of medial shift. Therefore, it would have been obvious to one of ordinary skill in the art to modify Bateman et al. to obtain the invention as specified in claim 125.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on September 8, 2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

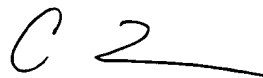
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3580 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0850.



Thomas Barrett
November 30, 2003



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700